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August 11, 2023

VIA ECF

The Honorable Leda D. Wettre, U.S.M.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street, Room 2060
Newark, New Jersey 07102

Re: *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*
Civil Action No. 23-1695 (MEF)(LDW)

Dear Judge Wettre:

This firm, together with Quinn Emanuel, represents Plaintiffs Axsome Therapeutics, Inc. and Antecip Bioventures II LLC (together, "Axsome") in this case. We write on behalf of Axsome and Defendant Teva Pharmaceuticals, Inc. ("Teva") to respectfully request that the Court resolve a dispute with respect to the parties' proposed Discovery Confidentiality Order ("DCO").

A draft of the proposed DCO is attached to this submission as Exhibit 1. The dispute relates to Paragraphs 9(b)(i)-(ii) of the proposed DCO, which are highlighted in Exhibit 1. The parties have diligently worked to reach agreement on all other provisions of the proposed DCO and have resolved many issues amongst themselves. However, the parties have been unable to reach agreement with respect to the inclusion of Paragraphs 9(b)(i)-(ii), and therefore respectfully ask the Court to determine whether the proposed DCO should be entered with or without those Paragraphs.

Teva's Position

Teva's proposal for narrow FDA and prosecution bars is tailored to a real and legitimate concern: in-house counsel who are given access to the confidential details of Teva's proposed ANDA product, manufacturing processes, and correspondence with the FDA ("Confidential Information") under the Discovery Confidentiality Order ("DCO") in this litigation should not be permitted to participate in FDA petitions regarding Teva's generic product, nor to participate in the prosecution of patents involving bupropion and dextromethorphan, including patents that could be listed in the Orange Book for Auvelity®. To address this concern, Teva's proposed prosecution and FDA bars would only preclude in-house counsel with access to Teva's Confidential Information from the following, until one year after a final, non-appealable judgment in this litigation:

> drafting or amending patent claims or providing recommendations regarding the drafting or amending of patent claims for any patents or patent applications that: (i) cover bupropion and dextromethorphan (including compositions, methods, distribution methods, uses or processes); and/or (ii) if issued, could be listed in the Orange Book for Auvelity® . . .
>
> [and]
>
> drafting or amending any petition or other correspondence before or involving FDA or any equivalent foreign agency concerning standards for approval of generic versions of Auvelity® or Teva's proposed ANDA product.

Teva's proposed bars are justified. The highly confidential information that Teva produces in this litigation about the status of its ANDA and the content of its discussions with the FDA are likely to contain competitively sensitive insights that would allow Plaintiffs to target citizens petitions to the FDA and/or new patent claims that unfairly harm Teva's ability to obtain timely approval of their ANDA product. For example, manufacturers of branded pharmaceutical products like Plaintiffs have regularly petitioned the FDA regarding approval of generic versions of the brand product, sometimes leading to substantial delay in the approval of those generic products regardless of the merits of the petitions.[1] Plaintiffs acknowledge that its counsel's use of Teva's confidential information for this purpose would be improper—it has not disputed the language of the use restriction provision in the DCO specifically prohibiting counsel from using Teva's "Confidential Information for any purpose other than in connection with this litigation, including for . . . communicating or petitioning activity with the FDA." Ex. 1 ¶ 9(b).

Regardless of intent, misuse of Teva's Confidential Information is unavoidable, if not inevitable, when the same in-house counsel responsible for reviewing Teva's Confidential Information in this litigation are also drafting or amending petitions to the FDA over the market entry of generic bupropion and dextromethorphan products, or drafting or amending patent claims regarding bupropion and dextromethorphan. As courts have recognized, "it is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so." *In re Deutsche Bank Tr. Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). Such misuse would also be extremely difficult to detect and remediate after the fact. For these reasons, Plaintiffs' proposal limited to the restriction in the proposed DCO that prohibits use of Teva's Confidential Information outside this litigation, including before the FDA or Patent Office, is an insufficient protection against inadvertent disclosure and use of such information.

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[1] *See, e.g.*, FDA Releases Final Guidance to Determine if Citizen Petitions Are Abusive, Center for Biosimilars (Sept. 20, 2019), https://www.centerforbiosimilars.com/view/fda-releases-finalguidance-to-determine-if-citizen-petitions-are-abusive; *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 691 (E.D. Pa. 2014), *reconsideration denied*, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015) (sham FDA citizens' petitions constitute anti-competitive conduct in pharmaceutical industry).

To guard against this inadvertent misuse, parties in similar patent litigations have regularly agreed to narrow prosecution and FDA bars, like the one proposed by Teva, without dispute. *E.g.*, *Alkermes, Inc. v. Teva Pharms. USA, Inc.*, 20-cv-12470, ECF No. 80 (D.N.J. Jan 18, 2022); *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, 20-cv-10172, ECF No. 53 (D.N.J. Feb. 3, 2021). And courts in this District and others have held that protective orders containing tailored FDA and prosecution bars, such as those sought here by Teva, are appropriate. *See, e.g.*, *Vivus, Inc. v. Actavis Lab'ys FL, Inc*., No. 14-CV-003786, 2016 WL 590212, at *4-5 (D.N.J. Feb. 11, 2016); *Digital Empire Ltd. v. Compal Elecs. Inc. Group*, No. 14-CV-1688-DMS(KSC), 2015 WL 10857544, at *3-8 (S.D. Cal. July 20, 2015); *Reckitt Benckiser Inc. v. Watson Laboratories, Inc.-Fla*., 09-60609-CIV, 2010 WL 11505200, at *5-7 (S.D. Fla. Mar. 11, 2010).

The fact that Plaintiffs have a small in-house legal department that focuses on Auvelity®, Plaintiffs' "centerpiece product," weighs in *favor* of Teva's proposal—not against it. *See Vivus*, 2016 WL 590212, at *4-5 (imposing FDA and prosecution bars where "the risk for inadvertent disclosure . . . [was] increased" by plaintiff's small, two-attorney in-house team, and by the fact that the patents at issue related to plaintiff's "centerpiece product"). As one court noted, "if the legal department is very small, that would tend to enhance such concerns" of inadvertent misuse of confidential information because it would not be possible to reassign any potentially conflicting assignments to a different in-house team or attorney. *PhishMe, Inc. v. Wombat Sec. Techs.*, No. CV 16-403-LPS-CJB, 2017 WL 4138961, at *7 (D. Del. Sept. 18, 2017) (holding that plaintiff's three-person in-house legal department, and the fact that one attorney "provides key legal advice directly to most or all of the corporate decision makers," weighed in favor of maintaining prosecution bar). Here, internet research indicates that Axsome's in-house attorneys hold the roles of General Counsel and Director, Commercial & Corporate Counsel[2]; both are high-ranking positions that presumably entail advice to the company's executives on competitive matters. The need for prosecution and FDA bars in this situation is apparent, and the threat of inadvertent disclosure and misuse is real and not speculative. *See Blackbird Tech LCC v. Serv. Lighting & Elec. Supplies,* No. CV 15-53-RGA, 2016 WL 2904592, at *4 (D. Del. May 18, 2016) (noting that a company's "small size and closely-held nature" "exacerbate[s] the potential for inadvertent misuse or disclosure," particularly where in-house counsel reported directly to competitive decision-makers); *Cytosport, Inc. v. Vital Pharms*., No. CIV S-08-2632 FCDGGH, 2010 WL 728454, at *4 (E.D. Cal. Mar. 2, 2010) ("The risk and potential danger of disclosure is compounded here in that VPX has only two attorneys on its in-house counsel team, and it is a relatively small company.").

Even if this means that none of Plaintiffs' in-house attorneys may ultimately obtain access to Teva's confidential information in this litigation, courts have "readily conclud[ed] that the outside counsel of a party's choice can adequately represent its interests even if in-house counsel is precluded from viewing confidential information." *See Blackbird*, 2016 WL 2904592, at *5 (collecting cases). For this reason, "[c]ourts have found time and again that requiring a party," here Plaintiffs, "to rely on its competent outside counsel does not create an undue or unnecessary burden." *ST Sales Tech Holdings, LLC v. Daimler Chrysler Co., LLC*, No. 6:07-CV-346, 2008

[2] Mr. Hunter Murdock, General Counsel (https://www.linkedin.com/in/hunter-murdock-15a1ba1a/) and Ms. Hanna Suh, Director, Commercial & Corporate Counsel (https://www.linkedin.com/in/hanna-suh-3663a4220/).

WL 5634214, at *8 (E.D. Tex. 2008). Indeed, the parties' joint proposal provides (¶ 19): "Nothing herein shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to this litigation and, in the course thereof, referring to or relying upon his or her examination of Confidential Information." Plaintiffs' reliance on the fact that Teva's proposal is limited to in-house counsel is inapposite. Teva understands that Plaintiffs' current outside counsel were not involved in the prosecution of the Asserted Patents, or Plaintiffs' patent portfolio more broadly, or in Plaintiffs' communications with FDA concerning its NDA for Auvelity®. The same is not true of Plaintiffs' few in-house attorneys who most likely were and continue to be involved in patent prosecution and FDA communications on behalf of the company.

For the above reasons, Teva respectfully requests that this Court implement Teva's proposed FDA and prosecution bars in the DCO for this matter.

Axsome's Position

The parties agree that up to four designated in-house counsel (*i.e.*, up to four employees of each party who meet certain criteria) may access Confidential Information ("CI") produced in this litigation. Teva, however, proposes that designated in-house counsel should be barred from (1) "engag[ing] formally or informally, directly or indirectly, in any U.S. or foreign patent prosecution" (a "patent prosecution bar"), and (2) "drafting or amending any petition or other correspondence before or involving the FDA concerning standards for approval of generic versions of Auvelity® or Teva's proposed ANDA product" (an "FDA bar"). Since Teva has failed to show the requisite good cause for its proposed bars, Axsome respectfully requests that the proposed DCO be entered without these provisions.

Fundamentally, the patent prosecution and FDA bars are unnecessary because the parties have already agreed on an explicit "use restriction": that in-house counsel with access to CI shall use that information ***only*** for purposes of this litigation and ***not*** for any other purpose, including patent prosecution and FDA petitioning:

> who, after receipt of Confidential Information, and in addition to the other terms of this Discovery Confidentiality Order, shall not use any other party's or any nonparty's Confidential Information for any purpose other than in connection with this litigation, including for any business, regulatory, commercial, or competitive purposes, including, but not limited to, filing or prosecuting patent applications or any communicating or petitioning activity with the FDA or another regulatory agency; and it shall be the duty of each party and each individual having notice of this Discovery Confidentiality Order not disclose any other party's or any nonparty's Confidential Information to any third party, including, but not limited to, the FDA and the PTO, and to otherwise comply with this Order from the time of such notice;

Ex. 1 at ¶9(b).

In fact, leading up to this dispute letter, Axsome proposed a strengthened use restriction in an effort to compromise with Teva and address its purported need for overly restrictive bars. But even this strengthened use restriction and binding agreement of Axsome's in-house counsel—all attorneys and officers of the court—is not good enough for Teva. Instead, Teva seeks to impose complete patent prosecution and FDA bars on all Axsome in-house attorneys with access to Teva's CI. Teva's proposal would prohibit those attorneys from engaging in any patent prosecution and any FDA correspondence related to the approval of generic versions of Auvelity® ***even if such correspondence has nothing to do with any of Teva's CI***.

Attorneys are trusted with confidences every day without the need for unduly burdensome bars that interfere with their ability to advise their clients. Teva fails to identify the particularized, unacceptable risk of inadvertent disclosure required by the Federal Circuit to justify its proposed bars.

As the party seeking to include patent prosecution and FDA bars in the protective order, Teva bears the burden of demonstrating that "good cause" exists for such bars. *See, e.g.*, *In re Deutsche Bank Tr. Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010).[3] This determination is a matter "governed by Federal Circuit law." *Id*. In *U.S. Steel Corp. v. United States*, the Federal Circuit held that "good cause" requires a showing of a ***concrete, particularized, unacceptable risk of inadvertent disclosure***. *See* 730 F.2d 1465, 1467-68 (Fed. Cir. 1984); *accord Deutsche Bank*, 605 F.3d at 1378-79. It is well-settled that "[t]he teaching of *U.S. Steel* and its progeny is that restrictions on access to confidential documents or the activities of counsel will not be imposed absent some specific, identifiable showing and not on the basis of broad generalizations of potential harm." *Warner Chilcott Labs. v. Impax Labs., Inc*., No. 08-6304, 2009 WL 3627947, at *3 (D.N.J. Oct. 29, 2009). To that end, generalized allegations of harm are not enough, and "[t]he notion that good cause can be shown simply by invoking the possibility of inadvertent disclosure has been rejected." *See id.* (rejecting "broad, blanket prohibitions applying to any lawyer that views confidential information, regardless of individual circumstances"). Further, any unacceptable risk must be balanced "against the potential harm to the opposing party from restrictions imposed on that party's right to have the benefit of counsel of its choice." *Deutsche Bank*, 605 F.3d at 1380. Teva's failure to identify any concrete, particularized risk necessary to justify including complete bars on any patent prosecution and Auvelity®-related FDA petitioning ends this dispute.

Teva's proposed patent prosecution and FDA bars lack good cause because Teva does not identify ***any*** concrete risks specific to this case that warrant patent prosecution or FDA bars in the DCO. *See U.S. Steel*, 730 F.2d at 1467-68; *Deutsche Bank*, 605 F.3d at 1378-79. At most, Teva merely identifies a generalized and speculative risk that its CI could be inadvertently disclosed or misused in connection with patent prosecution or FDA petitioning activities.

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[3] Teva cites to *Alkermes, Inc.* and *Teva Branded Pharm. Prods. R&D* to support its argument that "parties in similar patent litigations have regularly agreed to narrow prosecution and FDA bars, like the one proposed by Teva, without dispute." However, the undersigned has litigated countless Hatch-Waxman cases in this District where the parties agreed to ***not*** include such restrictive bars and, in any event, Teva's cases are inapplicable because Teva must still meet its burden to demonstrate good cause for its proposed bars here in view of the parties' dispute.

However, this hypothetical risk could be alleged in any Hatch-Waxman litigation. Teva's non-particularized, remote risks cannot justify the harm to Axsome and do not come close to meeting the good cause standard set forth in *U.S. Steel* and *Deutsche Bank*.

The use restriction that the parties have agreed to—which ***expressly prohibits the use of any of Teva's CI in patent prosecution or correspondence with the FDA***—is more than sufficient to address the generalized risk that Teva has articulated. In fact, the use restriction set forth in the proposed DCO is typical of most protective orders, while Teva's proposed bar is not. As the Federal Circuit has explained, "[t]ypically, protective orders include provisions specifying that designated confidential information may be used only for purposes of the current litigation. Such provisions are generally accepted as an effective way of protecting sensitive information while granting trial counsel limited access to it for purposes of the litigation." *Deutsche Bank*, 605 F.3d at 1378. Accordingly, courts in this District have previously found, and routinely find, that use restrictions alone are sufficient to protect parties' confidential information from being used improperly in Hatch-Waxman cases. *See, e.g.*, *Nautilus Neurosciences, Inc. v. Edict Pharms. Pvt. Ltd.,* No. 11-4183, D.I. 34, (D.N.J. Dec. 2, 2011); *Warner Chilcott Labs. v. Impax Labs., Inc*., No. 08-6304, D.I. 76 (D.N.J. Nov. 13, 2009); *Chiesi USA, Inc. v. Sandoz, Inc.*, No. 13-5723, D.I. 179 (D.N.J. Aug. 21, 2014).

With respect to its proposed patent prosecution bar, Teva has not pointed to anything about its CI that Axsome might inadvertently use to prosecute new patents. In fact, none of the patents in this case are directed to subject matter that could be unique to Teva's product. Even if one were to assume the untenable premise that Axsome would be willing to violate the use restriction, Teva does not articulate any subject matter that Axsome might inadvertently seek to copy. Thus, the risk of Teva's CI being used improperly for patent prosecution is de minimis. As such, Teva cannot show good cause for its proposed patent prosecution bar.

Similarly, Teva does not allege any particularized, unacceptable risk of inadvertent disclosure of Teva's CI in the absence of an FDA bar. Rather, Teva's rationale for including an FDA bar in the DCO, even if true, is nothing more than a generalized risk that is present in all Hatch-Waxman cases. Teva does not point to any specific action by Axsome that would support an FDA bar or anything about Teva's ANDA that it is concerned Axsome might use in a citizen petition. Accordingly, Teva's broad allegation of risk is insufficient to support its proposed bar. Thus, Teva has not shown good cause for including an FDA bar.

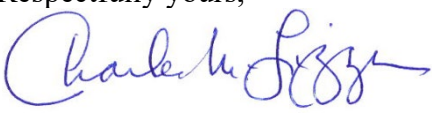
The generalized and speculative nature of Teva's argument is highlighted by the fact that Teva's proposed bars apply ***only*** to in-house counsel. Meaning, outside counsel who receive Teva's CI are ***not*** barred from engaging in patent prosecution or FDA petitioning. So, under Teva's proposal, the use restriction is good enough for outside—but not in-house—counsel. Teva fails to articulate any reason why outside and in-house counsel should be treated differently, and the case-law in this District is clear that "that the in-house status of counsel 'cannot alone create [a] probability of serious risk to confidentiality.'" *Sanofi-Aventis U.S. LLC v. Breckenridge Pharm., Inc.*, No. 15-289, 2016 WL 308795, at *2 (D.N.J. Jan. 25, 2016); *see also Razor USA LLC v. DGL Grp., Ltd*., No. 19-12939, 2020 WL 3604081, at *2 (D.N.J. July 2, 2020) ("Access to confidential information cannot be denied solely because of counsel's in-house status.").

At bottom, Teva's proposed patent prosecution and FDA bars lack good cause. Teva has not identified ***any concrete risks specific to this case*** that warrant including a patent prosecution or FDA bar. This is fatal to Teva's position. *See U.S. Steel*, 730 F.2d at 1467-68; *Deutsche Bank*, 605 F.3d at 1378-79. And, in more recent cases where defendants failed to articulate the requisite specificity to satisfy the good cause standard, courts in this District have expressly rejected patent prosecution and FDA petitioning bars on the basis that those defendants have failed to meet the "threshold burden of establishing that [the] proposed patent prosecution and FDA bar is a reasonable precautionary measure." *See, e.g.*, *Corcept Therapeutics v. Teva Pharm.*, C.A. No. 18-3632, ECF No. 73 (D.N.J. June 4, 2019). In *Corcept*, Judge Waldor found that the use restrictions similar to what has been agreed-upon here were more than sufficient to safeguard any confidential information. *Id.*[4] Stated differently, Teva's alleged broad, hypothetical risks cannot justify the harm of depriving Axsome the right to counsel of its choice.[5]

For the foregoing reasons, Axsome respectfully requests that the Court enter the proposed DCO attached as Exhibit 1, with the highlighted language in Paragraphs 9(b)(i)-(ii) stricken.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,



Charles M. Lizza

Exhibit
cc: All counsel of record (via email)

[4] The out-of-district cases on which Teva relies are inapposite and not controlling, and at least one of the cases expressly declined to follow authority from the Third Circuit in reaching its conclusions. *See Reckitt Benckiser Inc. v. Watson Labs., Inc. Fla.*, 2010 WL 11505200, at *4-5 (S.D. Fla. Mar. 11, 2010).

[5] Teva's reliance on Third Circuit cases is similarly misplaced. In *Vivus*, the patents were directed to formulations, not just methods of treatment covering administration according to the FDA approved label, as here. 2016 WL 590212, at *1. In *PhishMe*, the Protective Order contained three tiers (confidential, attorney's eyes only, and prosecution bar), and "the Court t[ook] note of the fact that the current Protective Order has been in place for over 10 months, and that (in light of the parties' competitive relationship) it was the product of significant negotiation." 2017 WL 4138961, at *1, *9. And in *Blackbird*, that the plaintiff was a non-practicing entity (which Axsome is not) supported the inclusion of bars. *See id.* at *6 ("To be sure, PhishMe is not a patent licensing entity, and so it is not that (as with such entities) its *entire business model* is built on the concept of bringing patent litigation and/or entering into patent licensing agreements.") (citing *Blackbird*, 2016 WL 2904592, at *2).

EXHIBIT 1

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Axsome Therapeutics, Inc. and
Antecip Bioventures II LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME THERAPEUTICS, INC., and ANTECIP BIOVENTURES II LLC,

Plaintiffs,

v.

TEVA PHARMACEUTICALS, INC.

Defendant.

Civil Action No. 23-1695 (MEF)(LDW)

PROPOSED STIPULATED DISCOVERY CONFIDENTIALITY ORDER

(Filed Electronically)

WHEREAS, Plaintiffs Axsome Therapeutics, Inc. ("Axsome") and Antecip Bioventures II LLC ("Antecip" and, collectively with Axsome, "Plaintiffs") and Defendant Teva Pharmaceuticals, Inc. ("Teva" or "Defendant") are the parties to Civil Action No. 23-1695 (MEF)(LDW) (the "action" or "litigation");

WHEREAS, the parties to this action believe that one or more of them will or may be required to disclose to another party certain documents, things, and information that constitute or contain trade secrets, technical know-how, or other confidential or proprietary research, development, business, commercial, or financial information relating to the subject matter of this action;

WHEREAS, the parties consider such information to be confidential and proprietary within the meaning of Fed. R. Civ. P. 26(c)(1)(G), *Pansy v. Borough of Stroudsburg*, 23 F.3d 772 (3d Cir. 1994) and *Glenmede Trust Co. v. Thompson*, 56 F.3d 476 (3d Cir. 1995) and, therefore, mutually desire that a Discovery Confidentiality Order limiting use, access to, and disclosure of such information be entered;

WHEREAS, to preserve the legitimate business interests of the parties or nonparties in their confidential information without unduly encroaching upon the public's right to be informed of judicial proceedings in accordance with Local Civil Rule 5.3;

WHEREAS, a party seeking to protect information filed under seal with the Court must show good cause for sealing that part of the record, in accordance with Local Civil Rule 5.3;

WHEREAS, the parties contemplate that confidential information produced in this action may be produced by a nonparty, and the parties also seek to facilitate the production and protection of such confidential information;

WHEREAS, the parties have exchanged and/or expect to exchange discovery in connection with this matter and recognize that confidential information may be disclosed in the course of this discovery, and in other proceedings in this matter;

WHEREAS, the parties desire to limit the extent of disclosure and use of such confidential information, and to protect such confidential information from unauthorized use and/or further disclosure, and wish to ensure that no advantage is gained by any party by the use of such confidential information which could not have been gained had discovery in this action not occurred;

WHEREAS, this action involves highly technical subject matter requiring discovery of trade secrets and proprietary information pertaining to, among other things, drug formulations, manufacturing processes and techniques, scientific research and development, and other sensitive competitive information; and

WHEREAS, the parties have consented to the entry of this Discovery Confidentiality Order pursuant to Fed. R. Civ. P. 26(c)(1)(G) and Local Civil Rule 5.3, and the Court having considered the foregoing and for good cause shown,

IT IS on this _____ day of _____, 2023,

ORDERED, that the following provisions shall govern the conduct of further proceedings in this action:

Definitions

1. The term "Confidential Information" shall mean any tangible thing or oral testimony that contains or reveals what a party or non-party considers to be its trade secret, business confidential, or proprietary research, development, commercial, or financial information. It may include, without limitation, documents produced in this action, during formal discovery or otherwise; information of non-parties which the producing or designating party is under an

obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such confidential information shall also be deemed "Confidential Information." Information originally designated as "Confidential Information" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act in good faith in designating information as "Confidential Information."

2. The term "party" means Axsome, Antecip and/or Teva.

3. The term "producing entity" means the party or nonparty producing documents or information as Confidential Information under this Order.

4. The term "receiving entity" shall mean the party to whom Confidential Information is produced.

Designation of Confidential Information

5. Each producing entity who produces or discloses any material that it believes comprises Confidential Information may so designate it by marking the document containing the information "CONFIDENTIAL." When documents are produced for inspection, the documents shall be treated by the receiving entity as "Confidential" until copies are provided and otherwise designated. Deposition testimony will be treated as Confidential Information unless: (1) otherwise designated; (2) confidentiality is waived either on the record during the deposition or in writing within twenty-five (25) calendar days after receipt of the transcript; or (3) the Court orders that such testimony is not Confidential. Each transcript shall be prominently marked on the front page with a statement that provides "THIS DEPOSITION TRANSCRIPT CONTAINS

CONFIDENTIAL INFORMATION SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER." For non-written material, such as recordings, magnetic media, photographs, and things, a legend substantially in the above form shall be affixed to the material, or a container for it, in any suitable manner.

6. If any Confidential Information is produced by a nonparty to this litigation, such a nonparty shall be considered a producing entity within the meaning of that term as it is used in the context of this Order and each of the parties shall be treated as a receiving entity. Confidential Information that originated with a nonparty may be designated as such and shall be subject to the restrictions on disclosure specified herein.

7. In the event any producing entity produces Confidential Information that has not been designated as such or not correctly designated, the producing entity may designate or redesignate the information to the same extent as it may have designated the information before production, by a subsequent notice in writing specifically identifying the redesignated information, in which event the parties shall henceforth treat such information in accord with this Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation, including retrieving any documents from persons not qualified to receive them under the redesignation and informing such persons that they should not further use or disseminate the information thereon. No demonstration or proof of error, inadvertence, or excusable neglect by the designating party shall be required for such redesignation, with the following exception: corrections to the designation of documents or information used in hearings, depositions, and trial must be made contemporaneously or else are waived, but only in situations where the nature of the hearing, deposition, or trial would otherwise be inconsistent with the designation sought (by way of nonlimiting example, redesignation must be contemporaneous in a public hearing where a

party seeks to designate a document as "Confidential," but redesignation need not be contemporaneous in a sealed hearing where a party seeks to designate a document as "Confidential"). If any document or information is: used during a deposition; used as an exhibit to a filing with the Court; identified for potential use at trial, including in expert reports or discovery responses, then the producing entity will be entitled to relief under this paragraph only if the producing entity makes a claim of inadvertent production within thirty (30) calendar days after such use or identification of the document or information.

8. A party shall not be obligated to challenge the propriety of any designation of Confidential Information at the time the designation is made, and failure to do so shall not preclude a subsequent challenge to the designation. In the event that any party to this action disagrees at any stage of this action with any designation, such party shall provide written notice of its disagreement with the designation to the producing entity. The parties shall first try to dispose of such dispute in good faith on an informal basis without judicial involvement. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court within ten (10) business days after written notice is provided, provided such request is in accordance with Local Civil Rule 37.1. The burden of proving that information has been properly designated is on the producing entity. However, the parties agree that designating information as Confidential Information is improper if such information (i) can be shown to be generally available to the public at the time of such designation; (ii) becomes part of the public domain or publicly known or available by publication or otherwise not as the result of any unauthorized act or omission on the part of the non-designating party; or (iii) is thereafter disclosed to the non-designating party by a third party as a matter of right.

Access and Use of Confidential Information

9. Subject to Paragraphs 13-18, Confidential Information of the producing entity may be disclosed, summarized, described, revealed, or otherwise made available in whole or in part only in accordance with the terms of this Order, and only to the following persons:

(a) Outside Counsel (herein defined as any attorney at the parties' outside law firms retained for purposes of this action) for Plaintiffs and Teva, and employees and agents of such counsel, who, after receipt of Confidential Information, and in addition to the other terms of this Discovery Confidentiality Order, shall not use any other party's or any nonparty's Confidential Information for any purpose other than in connection with this litigation;

(b) Up to four (4) designated in-house attorneys for each of Plaintiffs and Teva, respectively, as well as their clerical staff (including paralegals), who have a need to know Confidential Information to fulfill their duties and responsibilities in connection with this litigation, provided such attorneys have complied with Paragraph 15 hereof, the designated in-house attorneys for the parties being as follows:

For Plaintiffs: *to be determined*;

For Teva: *to be determined;*

who, after receipt of Confidential Information, and in addition to the other terms of this Discovery Confidentiality Order, shall not use any other party's or any nonparty's Confidential Information for any purpose other than in connection with this litigation, including for any business, regulatory, commercial, or competitive purposes, including, but not limited to, filing or prosecuting patent applications or any communicating or petitioning activity with the FDA or another regulatory agency; and it shall be the duty of each party and each individual having notice of this Discovery Confidentiality Order not disclose any

other party's or any nonparty's Confidential Information to any third party, including, but not limited to, the FDA and the PTO, and to otherwise comply with this Order from the time of such notice;

(i) For the length of this litigation plus one year after a final, non-appealable judgment in this litigation, any person receiving information designated as Confidential under Paragraph 9(b) may not engage formally or informally, directly or indirectly, in any U.S. or foreign patent prosecution. As used herein, "patent prosecution" means drafting and/or amending patent claims, but is not intended to preclude involvement in reexaminations, oppositions, inter partes review, covered-business-method review, patent nullity proceedings, or patent invalidation proceedings or similar post-grant proceedings before the U.S. Patent Office or any foreign patent office as long as such individuals are not involved directly or indirectly in drafting or amending patent claims or providing recommendations regarding the drafting or amending of patent claims) for any patents or patent applications that: (i) cover bupropion and dextromethorphan (including compositions, methods, distribution methods, uses or processes); and/or (ii) if issued, could be listed in the Orange Book for Auvelity®.

(ii) For the length of this litigation plus one year after a final, non-appealable judgment in this litigation, any person receiving information designated as Confidential under Paragraph 9(b) may not be involved directly or indirectly, in drafting or amending any petition or other correspondence before or involving FDA or any equivalent foreign agency concerning standards for approval of generic versions of Auvelity® or Teva's proposed ANDA product. Notwithstanding the

foregoing, nothing herein shall prevent a person from performing work before the FDA or any equivalent foreign agency solely for obtaining or maintaining approval of that parties' own new drug application, including related to the safety of a parties' own product, or abbreviated new drug application provided that no Confidential of the opposing party is used or disclosed.

(c) independent experts and consultants and their staff (excluding current and former directors and officers or employees or agents of the parties) retained to assist counsel for the parties in the conduct of this litigation, provided such persons have complied with Paragraph 15 hereof;

(d) potential fact witnesses in this action (including, but not limited to, those who were formerly directors, officers, employees, agents, or corporate designees of the producing entity), but only for those witnesses if the Confidential Information was in existence during the period of his or her service or employment (and foundation is established that the witness was privy to Confidential Information or was involved in the project to which the Confidential Information relates so that it is reasonable that the witness had access to the Confidential Information during the course of his or her service or employment) and their counsel, provided that the information was authored by, created by, addressed to, received by, signed by, or is otherwise established to have been known to the witness; but only at deposition, trial or court hearing, or in preparation thereof;

(e) the parties; in the case of parties that are corporations or other entities, "party" shall mean up to two (2) executives who are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit;

(f) the Court and its employees and the jury;

(g) court reporters and videographers;

(h) photocopy services;

(i) professional translators who are retained by the attorneys for the parties for the purposes of this litigation;

(j) graphics or design consultants retained to prepare demonstrative or other exhibits for use in this action;

(k) non-technical jury or trial consultants and persons employed or retained by them solely in providing litigation support services to the parties' outside counsel law firms;

(l) document imaging and database services and consultants retained to set up, maintain and/or operate litigation databases for this litigation; and

(m) any others as ordered by the Court or to whom the producing entity has given written consent.

10. Nothing in this Discovery Confidentiality Order shall prevent disclosure of Confidential Information if the producing entity consents to such disclosure or if the Court, after notice to all parties, orders such disclosure.

11. All Confidential Information disclosed pursuant to this Order shall be used by a recipient thereof solely for the purposes of this litigation and not for any business, regulatory, commercial, or competitive purposes, including, but not limited to, filing or prosecuting patent applications, engaging in any post-grant patent proceeding, or any communicating or petitioning activity with the FDA or another regulatory agency. It shall be the duty of each party and each

individual having notice of this Discovery Confidentiality Order to comply with this Order from the time of such notice.

12. By written agreement of the parties, or upon motion and order of the Court, the list of individuals designated under Paragraph 9 to whom Confidential Information may be disclosed may be modified or expanded.

13. If a producing entity seeks to protect Confidential Information from public disclosure or use during a trial, court appearance or hearing which is open to the public (a "Court Disclosure"), the receiving entity shall provide reasonable advanced notice of its intent to make a Court Disclosure and the producing entity shall make an application to the Court to restrict such disclosure or use, unless consent from the receiving entity is previously obtained. Such application may be made at any time before the Court Disclosure or within ten (10) business days after the Court Disclosure.

14. Any party filing any document, material or information designated by another party as "CONFIDENTIAL" shall comply with Local Civil Rule 5.3(c) to seal such document, material or information to prevent public disclosure. The parties will work together in good faith to jointly prepare the motion and supporting documents required by Local Civil Rule 5.3(c)(3).

Nothing in this provision relieves a party of liability for damages caused by the electronic filing of Confidential Information or for damages caused by failure to properly file under seal documents or materials containing Confidential Information.

15. No person identified in Paragraph 9(b)-(c) shall be given access to Confidential Information, respectively, unless such person shall first have signed a Declaration of Compliance with this Order in the form attached as Exhibit A hereto.

16. Before any person identified in Paragraphs 9(b)-(c) may be given access to Confidential Information, respectively, the party seeking to provide such access shall deliver a copy of the Declaration referred to in Paragraph 15, fully executed by such person, and written notice (by email) to the attorneys for the producing entity of the intention to make such disclosure. In the case of a disclosure to persons identified in Paragraph 9(b) hereof, the notice shall state the individual's name and position. In the case of a disclosure to persons identified in Paragraph 9(c) hereof, the notice shall state the name and address of the person to whom disclosure is proposed and include a curriculum vitae, an identification of the person's job title and responsibilities, and a list of cases in which, during the previous five (5) years, the expert or consultant has testified at trial or by deposition.

17. For proposed disclosures to persons identified in Paragraph 9(b)-(c) hereof, the producing entity, within five (5) business days from receiving service of written notice provided pursuant to Paragraph 16 hereof, may object to such disclosure by delivery (by email) of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information may occur prior to the expiration of five (5) business days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the producing entity or Ordered by the Court. Consent pursuant to the provisions of this paragraph shall not be unreasonably withheld. If the producing entity objects to the disclosure and gives written notice thereof, and the parties are unable to resolve the objection, the party opposing the disclosure must file a letter application to the Court pursuant to L. Civ. R. 37.1 within five (5) business days of giving the written notice of objection; otherwise, the information may be disclosed to the identified person. If such an application is made, no disclosure may be made until the objection is resolved by agreement of the designating and

receiving parties or the Court denies the application. Failure to timely object to the disclosure based on information then-disclosed in the written notice pursuant to Paragraph 16 hereof shall operate as a waiver of the objection. Waiver as to a specific disclosure shall not constitute waiver for any subsequent disclosures. In the event that an application is made, the objecting party shall have the burden of proving that disclosure should not occur.

18. Nothing herein shall prevent a producing entity from disclosing its own Confidential Information in any manner that it considers appropriate.

19. Nothing herein shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to this litigation and, in the course thereof, referring to or relying upon his or her examination of Confidential Information. In rendering such advice and in otherwise communicating with his or her client, counsel shall not disclose any Confidential Information if such disclosure would be contrary to the provisions of this Discovery Confidentiality Order.

20. If a party is served with a subpoena, discovery request in another action, or any other request seeking by legal process the production of documents, things, information or other material produced to it and designated as Confidential Information in this action, such party shall notify promptly the producing entity so as to provide the producing entity a reasonable opportunity to object to the production.

21. If an additional party joins or is joined in this action, the newly joined party shall not have access to Confidential Information until the parties agree to a supplemental Discovery Confidentiality Order governing the protection of Confidential Information.

22. Any third party from whom discovery is sought in this action may designate some or all of the documents, things, information or other material as Confidential Information under this Discovery Confidentiality Order. If it does so, then each party to the action will have with

respect to such Confidential Information the same obligations which that party has with respect to Confidential Information of another party to this action.

Duration of Order, Objections, Modifications

23. This Discovery Confidentiality Order shall remain in force and effect indefinitely until modified, superseded or terminated by Order of this Court, which may be entered pursuant to agreement of the parties hereto. This Discovery Confidentiality Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

24. Upon final termination of this action (including all appeals), the receiving entity shall, within sixty (60) calendar days of such termination, either return to the producing entity or destroy all Confidential Information in its possession, including, but not limited to, information stored in electronic form. In either event, the receiving entity shall describe the materials returned or destroyed and certify their return or destruction, with the exception that outside counsel may retain subject to the provisions of this Discovery Confidentiality Order one copy of the pleadings or other papers filed with the Court or served in the course of the litigation, deposition transcripts, deposition exhibits, hearing transcripts, and any hearing or trial record (including without limitation all bench memoranda, PowerPoint slides, and exhibits).

25. If the receiving entity desires to disclose Confidential Information to persons not qualified to receive it under this Order or if the receiving entity disagrees with a designation by the producing entity, then the receiving entity and the producing entity shall first try to resolve such dispute. If the dispute cannot be resolved, either party may seek a ruling from the Court. Pending a determination by the Court, such information shall be treated under this Order as Confidential Information as designated by the producing entity.

No Waiver of Privileges

26. If information that is otherwise properly subject to a claim of attorney-client privilege, attorney work-product immunity, or any other privilege or immunity protecting it from discovery is inadvertently produced, the fact or circumstances of such inadvertent production shall in no way be relied upon as a ground to support any argument that the information is no longer subject to the privilege or immunity. Nor shall such inadvertent production prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege, work product immunity or other ground for withholding production to which the producing entity or other person otherwise would be entitled, either in whole or in part, in this litigation or in any other proceeding. If a written claim of inadvertent production is made pursuant to this paragraph, upon receipt of such written notice, the receiving entity shall promptly destroy or return to the producing entity (i) the inadvertently produced material, (ii) any and all copies or reproductions thereof, and (iii) any and all copies of summaries or notes based thereon or relating thereto, of which the receiving entity is aware.

However, if the receiving entity wishes to challenge the claim that the information would have properly been subject to a privilege or immunity before it was inadvertently produced, it may retain one copy and must notify the producing entity of its challenge within ten (10) business days of receiving the notice of inadvertent production, and move the Court for a ruling on the propriety of the claim of privilege or immunity within ten (10) business days of receiving the notice of inadvertent production, unless such time period is extended by mutual agreement of the parties. During the pendency of such motion, the receiving entity may retain the single copy but shall make no other use or disclosure of the subject material or the information contained therein. The producing entity shall bear the burden of proving that the inadvertently produced documents or materials are privileged or immune from discovery. Within five (5) business days of the receiving

entity's timely filing of an application pursuant to L. Civ. R. 37.1 seeking an order compelling production of the inadvertently produced documents or materials, the producing entity shall provide to the Court's email address—LDW_orders@njd.uscourts.gov—a copy of the inadvertently produced documents or materials for *in camera* inspection by the Court. A copy of the cover letter forwarding the inadvertently produced information for *in camera* inspection by the Court shall be provided to the moving party. If the receiving entity prevails on its challenge to the producing entity's claim of privilege or immunity, the producing entity shall promptly reproduce the material to the receiving entity. If the receiving entity does not prevail on its challenge to the producing entity's claim of privilege or immunity, it must certify to the producing entity within five (5) business days of the Court's decision that it has destroyed the remaining single copy.

27. If any Confidential Information is disclosed through inadvertence or otherwise by a receiving entity to any person or party not otherwise authorized to receive such information under this Discovery Confidentiality Order, then the receiving entity responsible for the disclosure shall (i) use its best efforts to obtain the return of such information and to bind such non-authorized person or party to the terms of this Discovery Confidentiality Order; (ii) within three (3) business days of the discovery of such disclosure, inform such person or party of all provisions of this Discovery Confidentiality Order and request that such person or party sign the Declaration of Compliance with this Discovery Confidentiality Order in the form attached as Exhibit A hereto; and (iii) within five (5) business days of the discovery of such disclosure, inform the producing entity of all pertinent facts relevant to such disclosure, including the identity of such person or party and the information disclosed thereto.

No Waiver of Right to Appropriately Withhold or Redact

28. Notwithstanding the provisions of this Discovery Confidentiality Order, parties may redact from any document, whether or not designated Confidential Information under this

Order, any information containing privileged material or material protected by work-product immunity.

Amendment

29. This Discovery Confidentiality Order may be amended with respect to (a) specific documents or items of Confidential Information, or (b) persons to whom Confidential Information may be disclosed, upon written agreement of the parties with the approval of the Court. This Discovery Confidentiality Order shall remain in force and effect indefinitely until modified, superseded, or terminated by order of this Court.

Other Remedies

30. Nothing herein shall prevent any party or nonparty from seeking additional or different relief from the Court not specified in this Order.

Miscellaneous

31. No party shall be responsible to another party for any use made of information that was produced and not designated as Confidential Information, except to the extent a party is required to perform the duties set forth in Paragraph 7 above.

32. Nothing in this Discovery Confidentiality Order shall prejudice the right of any party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

33. Nothing in this Discovery Confidentiality Order shall prejudice the right of any party to seek at any time a further order modifying this Discovery Confidentiality Order.

34. In the event that a new party is added, substituted, or brought in, this Discovery Confidentiality Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Discovery Confidentiality Order.

35. Notice under this Discovery Confidentiality Order shall be to the parties as follows, unless this provision is modified by the parties in writing: notice to Plaintiffs shall be made to F. Dominic Cerrito, Quinn Emanuel Urquhart & Sullivan, LLP, 51 Madison Avenue, 22nd Floor, New York, NY 10010, nickcerrito@quinnemanuel.com, and notice to Teva shall be made to Alexandra D. Valenti, Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, NY 10018.

36. In the event any provision of this Order is inconsistent with the Court's Local Civil Rules, the latter shall control.

IT IS SO STIPULATED AND AGREED this __ day of _____, ____:

s/ DRAFT
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Attorneys for Defendant
Teva Pharmaceuticals, Inc.

IT IS SO ORDERED:

_____ Dated: _____

Hon. Leda D. Wettre, U.S.M.J.

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME THERAPEUTICS, INC., and ANTECIP BIOVENTURES II LLC, **Plaintiffs,** **v.** **TEVA PHARMACEUTICALS, INC.** **Defendant.**	**Civil Action No. 23-1695 (MEF)(LDW)**

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I live at _____. I am employed as (state position) _____ by (state name and address of employer) _____.

2. I have read the Discovery Confidentiality Order entered in this case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Discovery Confidentiality Order, including that upon receipt of any Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

4. I agree that I will be subject to the jurisdiction of the United States District Court for the District of New Jersey for purposes of enforcement of the Discovery Confidentiality Order.

5. I understand that unauthorized disclosure of any designated Confidential Information, or its use for any purpose other than this litigation, may constitute contempt of this

Court and may subject me to sanctions or other remedies that may be imposed by the Court and or potential liability in a civil action for damages by the producing entity.

6. At the final termination of this litigation, I will return to counsel or destroy all documents or things consisting of or containing Confidential Information.

7. I declare, as provided by 28 U.S.C. Section 1746, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed this _____ day of _____, 20__.

_____